

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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				Complete if Known			
		Application Number	10/579,357				
		Filing Date	May 16, 2006				
		First Named Inventor	Reinhard BOLLI				
		Art Unit	1644				
		Examiner Name	Yunsoo KIM				
		Attorney Docket Number	06478.1507-00000				
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U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
10	4,396,608		08-02-1983	Tenold	
11	4,439,421		03-27-1984	Hooper et al.	
12	4,499,073		02-12-1985	Tenold	
13	4,849,508		07-18-1989	Magnin et al.	
14	4,880,913		11-14-1989	Doleschel et al.	
15	5,164,487		11-17-1992	Kothe et al.	
16	5,177,194		01-05-1993	Sarno et. Al.	
17	5,593,675		01-14-1997	Hodler, et al.	
18	6,069,236		05-30-2000	Burnouf-Radosevich et al.	
19	6,162,904		12-19-2000	Mamidi et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Country Code Number Kind Code (if known)				
20	DE 2 364 792		07-18-1974	South African Inventions Development Corp.		English abstract
21	DE 3 430 320 A1		03-28-1985	Nihon Seiyaku Co., Ltd.		English abstract
22	DE 4 118 912 C1		07-02-1992	Biotech Pharma GmbH		English abstract
23	EP 0 447 585 B1		05-03-1995	Biotech Pharma GmbH		English counterpart
24	EP 0 893 450 A1		01-27-1999	Bayer Corporation		
25	EP 0 911 037 A1		04-28-1999	Yoshitomi Pharmaceutical Industries, Ltd.		
26	EP 1 084 147 B1		09-29-2004	Statens Serum Institut		
27	EP 1 268 551 B1		02-25-2004	Amersham Biosciences AB		
28	WO 94/29334		12-22-1994	Association Pour L'Essor De La Transfusion Sanguine Dans La Region Du Nord		English counterpart

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FOREIGN PATENT DOCUMENTS

29	WO 96/15153	05-23-1996	Baxter International Inc. et al.		
30	WO 98/05686	02-12-1998	CSL Limited		
31	WO 99/64462	12-16-1999	Statens Serum Institut		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
	32	Andersson, I. et al., "An Improved Chromatography Method For Production Of IgG From Human Plasma," Presented at XXIII Congress of the International Society of Blood Transfusion (1994).	
	33	Azulay, J.-P. et al., "Intravenous Immunoglobulin Treatment In Patients With Motor Neuron Syndromes Associated With Anti-GM ₁ Antibodies, A Double-Blind, Placebo-Controlled Study." Neurology, Vol. 44, pp. 429-432 (1994).	
	34	Basta, M. et al., "High-Dose Intravenous Immunoglobulin Exerts its Beneficial Effect in Patients with Dermatomyositis by Blocking Endomysial Deposition of Activated Complement Fragments," The Journal of Clinical Investigation Inc., Vol. 94, pp. 1729-1735 (1994).	
	35	Berkman, S.A. et al., "Clinical Uses of Intravenous Immunoglobulins," Annals of Internal Medicine, Vol. 112, pp. 278-292 (1990).	
	36	Biesert L., "Virus Validation Studies of Immunoglobulin Preparations," Clinical and Experimental Rheumatology, Vol. 14, Suppl. 15, pp. S47-S52 (1996).	
	37	Bjorkander, J. et al., "1040 Prophylactic Infusions with an Unmodified Intravenous Immunoglobulin Product Causing Few Side-Effects in Patients with Antibody Deficiency Syndromes," Infection Vol. 13, No. 3, pp. 102-110 (1985).	
	38	Brenner, B., "Clinical Experience With Octagam, A Solvent Detergent (SD) Virus Inactivated Intravenous Gammaglobulin," Clinical and Experimental Rheumatology, Vol. 14 , Suppl. 15, pp. S115-S119 (1996).	
	39	Buckley, R.H. et al., "The Use of Intravenous Immune Globulin in Immunodeficiency Diseases," The New England Journal of Medicine, Vol. 325, No. 2, pp. 110-117 (1991).	
	40	Cassulis, P. et al., "Ligand Affinity Chromatographic Separation of Serum IgG on Recombinant Protein G-Silica," Clin. Chem., Vol. 37, No. 6, pp. 882-886 (1991).	
	41	Clerc, M.-F. et al., "Labelling of Colloidal Gold with IgE," Histochemistry, Vol. 89, pp. 343-349 (1988).	
	42	Cooperative Group For the Study of Immunoglobulin in Chronic Lymphocytic Leukemia, "Intravenous Immunoglobulin for the Prevention of Infection in Chronic Lymphocytic Leukemia, A Randomized, Controlled Clinical Trial," The New England Journal of Medicine, Vol. 319, pp. 902-907 (1988).	

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4

NON PATENT LITERATURE DOCUMENTS		
43	Dalakas, M.C., "Intravenous Immune Globulin Therapy for Neurologic Diseases, Annals of Internal Medicine," Annals of Internal Medicine, Vol. 126, No. 9, pp. 721-730 (1997).	
44	Dwyer, J.M., "Manipulating the Immune System with Immune Globulin," The New England Journal of Medicine, Vol. 326, No. 2, pp. 107-116 (1992).	
45	El Alaoui, S. et al., "Development of an Immunocapture Method for Measuring IgA Antibodies to Tissue Transglutaminase in the Sera of Patients with Coeliac Disease," Clinical and Experimental Immunology, Vol. 144, pp. 101-109 (2006).	
46	Gammagard S/D, "Humanes Immunoglobulin Zur Intravenosen Anwendung Solvent/Detergent Behandelt," Product Information, Baxter Deutschland GmbH, Edisonstr. 3-4, D-85716 Unterschleißheim, Germany (1994).	Statement of Relevance
47	Habeb A.F.S.A. et al., "Preparation of Human Immunoglobulin by Caprylic Acid Precipitation," Preparative Biochemistry, Vol. 4, No. 1, pp. 1-17 (1984).	
48	Hansen P. et al., "Isolation and Purification of Immunoglobulins from Chicken Eggs Using Thiophilic Interaction Chromatography," J. Immunological Methods, Vol. 215, pp. 1-7 (1998).	
49	Harris, J.R., Ed., "Blood Separation and Plasma Fractionation," pp. 332-333, Wiley-Liss, New York (1991).	
50	Hocini H. et al., "An ELISA Method to Measure Total and Specific Human Secretory IgA Subclasses Based on Selective Degradation by IgA1-Protease," J. Immunological Methods, Vol. 235, No. 1-2, pp. 53-60 (2000) (Abstract).	
51	Kaveri, S.-V. et al., "Intravenous Immunoglobulins (IVIg) In The Treatment Of Autoimmune Diseases," Clinic Exp. Immunol., Vol. 86, pp. 192-198 (1991).	
52	Koopman W.J. et al., "A Sensitive Radioimmunoassay for Quantitation of IgM Rheumatoid Factor," Arthritis and Rheumatism, Vol. 23, No. 3, pp. 302-308 (1980).	
53	Lundblad, J.L. et al., "Comparative Studies of Impurities in Intravenous Immunoglobulin Preparations," The University of Chicago, Reviews of Infectious Diseases, Vol. 8, Supp. 4, pp. S382-S390 (1986).	
54	McCue, J.P., "Changes in Therapeutic Proteins Caused by Preparation Techniques," Annals of Internal Medicine, Vol. 111, No. 4, pp. 271-272 (1989).	
55	Mollnes, T.E. et al., "Effect of Whole and Fractionated Intravenous Immunoglobulin on Complement In Vitro," Molecular Immunology, Vol. 34, No. 10, pp. 719-729 (1997).	
56	Nourichafi, N. et al., "Comparison of various chromatographic supports for purifying human plasmatic immunoglobulins from Cohn II + III fraction," Biotechnology of Blood Proteins, Vol. 227, pp. 207-212 (1993).	
57	Nydegger, U.E., "Sepsis and Polyspecific Intravenous Immunoglobulins," Journal of Clinical Apheresis, Vol. 12, pp. 93-99 (1997).	
58	Oldham, G. et al., "A Quantitative Method for Measuring in vitro Synthesis of IgA and IgG by Human Rectal Mucosa: Studies on normal controls and patients with hypogammaglobulinaemia," Immunology, Vol. 37, pp. 661-668 (1979).	

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NON PATENT LITERATURE DOCUMENTS		
59	Scopes, R.K., "Protein Purification, Principles and Practice," 2nd Edition, pp. 42-45, published in "Springer Advance Texts In Chemistry," series editor Charles R. Cantor, Springer-Verlag, N.Y. (1987).	
60	Stucki, M. et. al., "Characterisation Of A Chromatographically Produced Anti-D Immunoglobulin Product," Journal of Chromatograph B., Vol. 700, pp. 241-248 (1997).	
61	Waldo, F.B. et al., "Mixed IgA-IgG Aggregates As A Model Of Immune Complexes In IgA Nephropathy," The Journal of Immunology, Vol. 142, No. 11, pp. 3841-3846 (1989).	
62	Wang, W., "Antibody Structure, Instability, and Formulation," Journal of Pharmaceutical Sciences, Vol. 96, No. 1, pp. 1-26 (2007).	
63	Wells, J.V. et al., "Cord Serum IgA Levels in Australian Infants," J. Paediatrics and Child Health, Vol. 16, No. 3, pp. 189-90 (1980) (Abstract).	
64	English Language Derwent abstract of DE 2 364 792. , 1974	
65	English Language Derwent abstract of DE 3 430 320 A1. 1985	
66	English Language Derwent abstract of DE 4 118 912 C1. 1986	

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